## REMARKS

In view of the following remarks responsive to the Office Action of February 10, 2004, Applicant respectfully requests favorable reconsideration of this application.

Claims 1-18 are pending in this application. Claims 19-26 have been withdrawn from consideration in view of the previous restriction requirement.

Applicant respectfully thanks the Office for the indication that claim 16 is merely objected to as depending from a base claim but would be allowable if rewritten in that form.

The remaining claims, claims 1-15, 17, and 18, have been rejected as obvious over the combination of Vrba and Alt.

### The Present Invention

The present invention pertains to a stent delivery system particularly adapted to assure that the stent is not moved by the delivery apparatus in the body lumen inadvertently during the implantation process. Particularly, the stent delivery mechanism comprises a catheter having an outer tube and an inner tube designed to hold the stent therein in a radially constricted condition by one or more inflatable balloons carried on the inner tube at or near the location of the loaded stent. More specifically, the stent is positioned between the outer surface of an inner tube and the inner surface of the outer tube. The balloon or balloons may be axially aligned with the stent, i.e., the stent is mounted over the balloons on the inner tube.

For implantation, the assembly is inserted into the body lumen with the outer tube essentially protecting the stent. The outer tube and inner tube are not moved relative to each other during this positioning. When the entire assembly is positioned so that the stent is in the desired deployment position, the balloon is inflated to an internal pressure or volume that is small enough so that the frictional force between the balloon and the inner surface of the outer tube is not so great that it is impossible or difficult to slide the outer tube relative to the inner tube and balloons yet is high enough to keep the stent from moving with respect to the inner tube when the outer tube is slid relative to the inner tube of the balloon. The outer tube is then withdrawn, thereby exposing the stent to the vessel. The balloon should be formed of a material that is more compliant than the outer tube so that the balloon will take a greater set against the stent than it will against the outer tube, thus holding the balloon in place longitudinally relative to the inner tube when the outer tube is moved longitudinally.

**The Vrba Reference**

Vrba discloses a stent comprising a self-expanding stent portion and a balloon expandable stent portion and the rudimentary aspects of an associated delivery apparatus. In the delivery apparatus, the self expanding part of the stent is positioned within a retractable sheath 20 and the balloon expandable portion is positioned over a balloon (Figure 2 and col. 2, lines 17-26. The sheath is retracted to permit the self expanding portion to self expand and then the balloon is inflated to expand the balloon expandable portion (Figure 3 and co. 2, lines 35-

49). As the Office concedes, Vrba does not teach one of the basic tenets of the present invention, i.e., trapping the stent between the balloon and the inner surface of an outer sheath. Particularly, the balloon (which is adjacent only the balloon expandable portion of the stent) remains deflated until after the retractable sheath is withdrawn.

**The Alt Reference**

Alt discloses a stent delivery apparatus in which a balloon is positioned at the end of a tube and a balloon expandable stent is crimped to the outer surface of the balloon. The axial length of the balloon is greater than the axial length of the stent so that the balloon axially extends both proximally and distally of the stent. Alt discloses the step of the slightly inflating balloon to a pressure low enough that it does not expand the stent, but so that the proximal and distal ends of the balloon that extend beyond the axial extremes of the stent do expand to a diameter greater than the stent. There is no outer tube within which the stent and balloon are contained. The stent is completely exposed within the body lumen during insertion of the catheter. The radial expansion of the proximal and distal ends of the balloon beyond the radial diameter of the stent in combination with crimping the stent to the balloon assures that the stent does not slide longitudinally on the balloon during advancement.

When the catheter has been advanced so that the stent (and balloon) is at the deployment site, the balloon is then fully expanded to cause the stent to expand to meet the walls of the body lumen. The balloon is then deflated and

the catheter and guide wire are then removed, leaving the stent in place. The balloon does not trap the stent between the balloon and the inner surface of the outer tube in Alt. There is no outer tube in Alt. The stent is exposed within the body lumen during advancement.

**The Rejection**

The Office argues that Vrba discloses all of the claim elements of the rejected claims except for "inflating the balloon so as to trap a stent between the balloon and an outer tube". However, the Office argues (as it did in the previous Office Action) that Alt discloses "slight inflating the balloon at the ends to prevent a stent from being dislodged and retaining the stent firmly centered along the balloon's length during delivering". The Office then concluded that is was obvious to modify Vrba "by adding the step of inflating a balloon in order to retain the stent firmly on the balloon during delivering".

**Applicant's Response to the Rejection**

There are three elements that must be established to support an obviousness rejection, namely, all of the elements of the claim are present in the prior art references, there is a suggestion in the prior art to make a combination of the references that would result in the claimed invention, and that there would be an expectation of success in making the proposed combination.

Clearly, the most fundamental requirement of an obviousness rejection is not met here. Alt does not teach trapping the stent between the balloon and an

outer tube. Alt teaches the entirely different concept of trapping the stent between the opposite ends of the balloon.

Accordingly, the present invention cannot possible be made obvious by Vrba and Alt. Neither reference teaches trapping the stent between a balloon and the inner surface of an outer tube. Hence, all claims as currently pending patently distinguish over Vrba and Alt in combination.

Referring to independent claim 1, for instance, the prior art of record does not disclose at least "inflating said balloon so as to trap said stent between said balloon and said outer tube" as claimed in claim 1.

All other claims depend from claim 1 and, therefore, distinguish over the prior art of record for at least all of the reasons discussed above in connection with claim 1.

In view of the foregoing amendments and remarks, this application is now in condition for allowance. Applicant respectfully requests the Examiner to issue a Notice of Allowance at the earliest possible date. The Examiner is invited to contact Applicant's undersigned counsel by telephone call in order to further the prosecution of this case in any way.

Respectfully submitted,

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